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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 97,195-P)

In re Application of:

Burg, et al.

Serial No.: 09/901,181

Filed: July 9, 2001

For: Nucleic Acid Assays

Commissioner for Patents
P.O. Box 1450

TRANSMITTAL LETTER

Dear Sir:

In regard to the above identified application,

- 1. We are transmitting herewith the attached:
 - a) Petition to Withdrawn the Holding of Abandonment
- 2. With respect to fees:

Alexandria, VA 22313-1450

- a) It is believed that no fee is due at this time.
- a) Please charge any underpayment or credit any overpayment our Deposit Account No. 13-2490.
- 3. CERTIFICATE OF FACSIMILE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1, are being faxed to the Asst. Commissioner for Patents, Washington, D.C. 20231 on July 6, 2004 at 703-308-7751.

Date: July 6, 2004

Lisa M.W. Hillman, Ph.D

Respectfully submitted.

Reg. No. 43,673

BEST AVAILABLE COPY

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 97,195-P)

In re Application of:	
Burg, et al.)) JUL 2 6 2004
Serial No.: 09/901,181) Examiner: TBA CREET FETTICE:
Filed: July 9, 2001) Art Unit: 1656
For: Nucleic Acid Assays).

PETITION TO WITHDRAW THE HOLDING OF ABANDONMNET

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully petition to withdraw the holding of abandonment issued in the above-mentioned application on June 1, 2004 for failure to reply to the Notice of Missing Parts mailed on August 6, 2001. It is believed that no fee is due in connection with this filing; however, if a fee is due the Commissioner is authorized to charge our deposit account number 13-4950.

A complete, timely reply to the Notice to File Missing Parts issued on August 6, 2001 was filed with the USPTO on September 10, 2001. A true copy of the originally filed reply is attached. Also attached is a copy of a properly itemized date-stamped postcard receipt. Additionally, the original reply contained a certificate of mailing in compliance with 37 CFR 1.8(a). See point number 4 of Transmittal letter dated Sept. 10, 2001. The undersigned signed the certificate of mailing on September 10, 2001 and attests, based on personal knowledge, that the response was indeed timely mailed on September 10, 2001.

Applicants respectfully request the withdrawal of the holding of abandonment issued in this application on June 6, 2001.

Respectfully submitted,

Date:

July 6, 2004

Cartal V Hillman Bl. D

Lisa M.W (Hillman, Ph.D Registration No. 43,673



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United Status Patent and Trademark Office
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FILING OR 371(C) DATE FIRST NAMED APPLICANT ATTY, DOCKET NO /TITLE

APPLICATION NUMBER 09/901.181

07/09/2001

J. Lawrence Burg

97.195-P

JUL 2 6 2004

CONFIRMATION NO. 6516

ABANDONMENT/TERMINATION

MCDONNELL BOEHNEN HULBERT & BERGHOFF LUPTURE CREEK 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606

PETTER

OC000000012825921

Date Mailed: 06/01/2004

NOTICE OF ABANDONMENT UNDER 37 CFR 1.53 (f) OR (g)

The above-identified application is abandoned for failure to timely or properly reply to the Notice to File Missing Parts (Notice) mailed on 08/06/2001.

No reply was received.

A petition to the Commissioner under 37 CFR 1.137 may be filed requesting that the application be revived.

Under 37 CFR 1.137(a), a petition requesting the application be revived on the grounds of UNAVOIDABLE DELAY must be filed promptly after the applicant becomes aware of the abandonment and such petition must be accompanied by: (1) an adequate showing of the cause of unavoidable delay; (2) the required reply to the aboveidentified Notice; (3) the petition fee set forth in 37 CFR 1.17(I); and (4) a terminal disclaimer if required by 37 CFR 1.137(d).

Under 37 CFR 1.137(b), a petition requesting the application be revived on the grounds of UNINTENTIONAL DELAY must be filed promptly after applicant becomes aware of the abandonment and such petition must be accompanied by: (1) a statement that the entire delay was unintentional; (2) the required reply to the aboveidentified Notice; (3) the petition fee set forth in 37 CFR 1.17(m); and (4) a terminal disclaimer if required by 37 CFR 1.137(d).

Any questions concerning petitions to revive should be directed to the "Office of Petitions" at (703) 305-9282 Petitions should be mailed to: Mail Stop Petitions, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

A copy of this notice MUST be returned with the reply.

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

Notice of Abandonment

This application is abandoned in view of applicant's failure to timely file a proper reply to the Office notice mailed on O-1-C

Petition to Withdraw the Holding of Abandonment

If a complete reply to the notice was previously filed by applicant within the time period set forth in the notice, applicant may request for reconsideration of the holding of abandonment within 2 months from the mailing of this notice of abandonment by filing a petition to withdraw the holding of abandonment under 37 CFR 1.181(a). No petition fee is required. The petition must be accompanied by a true copy of the originally filed reply and the item(s) identified in one of the following:

- 1. A properly itemized date-stamped postcard receipt (see MPEP § 503);
- 2. If the originally filed reply included a certificate of mailing or transmission in compliance with 37 CFR 1.8(a), a copy of the certificate of mailing or transmission and a statement in compliance with 37 CFR 1.8(b) (see MPEP § 512); or
- 3. If the reply was filed via Express Mail, a submission satisfying the requirements of 37 CFR 1.10(e) including, for example, a copy of the Express Mail mailing label showing the "date-in" (see MPEP §

Any petition to withdraw the holding of abandonment should be transmitted by facsimile directly to OIPE Customer Service at (703) 308-7751.

Petition to Revive an Abandoned Application

If applicant did not previously file a complete reply within the time period set forth in the notice, applicant may file a petition to revive the application under 37 CFR 1.137.

Under 37 CFR 1.137(a), a petition requesting the application be revived on the grounds of UNAVOIDABLE DELAY must be filed promptly after the applicant becomes aware of the abandonment and such petition must be accompanied by:

- 1. an adequate showing of the cause of unavoidable delay;
- 2. the required reply to the above-identified notice;
- 3. the petition fee set forth in 37 CFR 1.17(i); and
- 4. a terminal disclaimer if required by 37 CFR 1.137(d).

See MPEP § 711.03(c) and Form PTO/SB/61.

Under 37 CFR 1.137(b), a petition requesting the application be revived on the grounds of UNINTENTIONAL DELAY must be filed promptly after applicant becomes aware of the abandonment and such petition must be accompanied by:

- 1. a statement that the entire delay was unintentional.
- 2. the required reply to the above-identified notice;
- 3. the petition fee set forth in 37 CFR 1.17(m); and
- 4. a terminal disclaimer if required by 37 CFR 1.137(d).

See MPEP § 711.03(c) and Form PTO/SB/64.

Any questions concerning petitions to revive should be directed to Office of Petitions at (703) 305-9282.

Any questions regarding this notice should be directed to OIPE Customer Service at (703) 308-1202.

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 97,195-P)

In re Application of:)	
Burg, et al.)	
Serial No.: 09/901,181) Examiner: TB.	Ą
Filed: July 9, 2001) Art Unit: 1656	5
For: Improved Nucleic Acid Assays	.)	

TRANSMITTAL LETTER

Asst. Commissioner for Patents Washington, D.C. 20231

Dear Sir:

In regard to the above identified application,

- 1. We are transmitting herewith the attached:
 - a) Amendment and Response to Notice to File Missing Parts;
 - b) Drawings (30 sheets);
 - c) Request for Corrected Filing Receipt;
 - d) Return postcard
- 2. With respect to fees:

No fee is required at this time.

- GENERAL AUTHORIZATION: Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed.
- 4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Asst. Commissioner for Patents, Washington, D.C. 20231 on September 10, 2001.

Respectfully submitted,

Date: September 10, 2001

Lisa M.W. Hillman Registration No. 43,673

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:) Oroup Art Unit: 1656
Burg et al.)) Examiner: TBA
Serial No: 09/901,181) Atty Docket No.: 97-195P
Filed: July 9, 2001)
For: Improved Nucleic Acid Assays)
	·

AMENDMENT AND RESPONSE TO NOTICE TO FILE MISSING PARTS

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

This paper is filed in response to the Notice to File Missing Parts mailed on August 6, 2001. It is believed that no fee is due in connection with this filing. However, if a fee is due the Commissioner is authorized to charge our Deposit Account No. 13-2490. Please enter the following amendment:

IN THE SPECIFICATION:

Please amend the first paragraph of the application to read:

This is a continuation of application U.S. Ser. No. 09/245,939, filed Feb. 5, 1999, which is a divisional application of U.S. Serial No. 08/850,171, filed May 2, 1997, now abandoned.

Remarks

The specification has been amended to provide reference to related applications.

No new matter has been added by this amendment. A marked-up version of the paragraph appears in Appendix A.

Sequence Rules Compliance

The Office has objected to the specification as not complying with the sequence listing rules. Applicants traverse this objection and respectfully submit that the rejection is improper. A sequence listing is not required for the following reasons:

- 1. No claims are presented directed to nucleic acid sequences; and
- 2. 37CFR 1.821 1.825 as amended and published as Final Rules in the Official Gazette, February 20, 2001, vol. 1243/No.3/Book 1 of 2, pp.241-257 mandate that these sections "are not mandatory" (p.242, right column, last full paragraph) for applications that claim the benefit of a prior application under 35 U.S.C. 120 filed before July 1, 1998, and which do not add subject matter involving a sequence listing subject to 1.821-1.825 (id., left column, Applicability Date).

This application claims priority to and is a continuation application of Ser. No. 09/245,939, filed Feb. 5, 1999, which is a divisional application of Serial No. 08/850,171, filed on May 2, 1997. Therefore, a sequence listing is not required for this application. Applicants respectfully request withdrawal of the requirement.

The Drawings

Substitute Drawing sheets are enclosed. Applicants believe that the Substitute Drawings comply with 37 C.F.R. 1.84.

Respectfully submitted,

Lisa M.W. Hillman

Registration No. 43,673

McDonnell Boehnen Hulbert & Berghoff

300 South Wacker Drive Chicago, Illinois 60606 Telephone: (312) 913-0001 Facsimile: (312) 913-0002

APPENDIX A

Marked-up Version to Show Changes Made to the Specification

This is a continuation of application U.S. Ser. No. 09/245,939, filed Feb. 5, 1999, which is a divisional application of U.S. Serial No. 08/850,171, filed May 2, 1997, now abandoned.



United States Patent and Trademark Office

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER FILING/RECEIPT DATE FIRST NAMED APPLICANT ATTORNEY DOCKET NUMBER

09/901,181 07/09/2001

J. Lawrence Burg

97,195**-**P

20306 MCDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE SUITE 3200 CHICAGO, IL 60606



Date Mailed: 08/06/2001

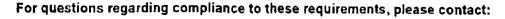
NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

This application has been accorded an Application Number and Filing Date. The application, however, is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given **TWO MONTHS** from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a)

The required item(s) identified below must be timely submitted to avoid abandonment:

- Substitute drawings in compliance with 37 CFR 1.84 because:
 - drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. (5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch);
 - drawings submitted to the Office are not electronically reproducible. Drawing sheets
 must be submitted on paper which is flexible, strong, white, smooth, non-shiny, and
 durable (see 37 CFR 1.84(e));
- This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.



- For Rules Interpretation, call (703) 308-4216
- To Purchase Patentin Software, call (703) 306-2600
- For Patentin Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

A copy of this notice MUST he returned with the reply.

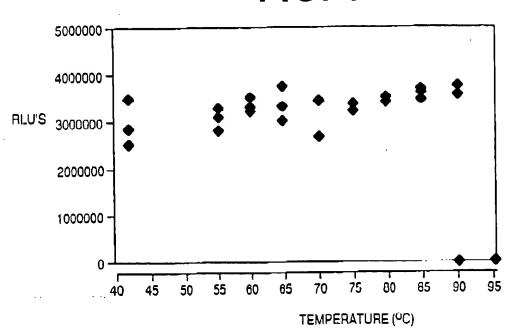
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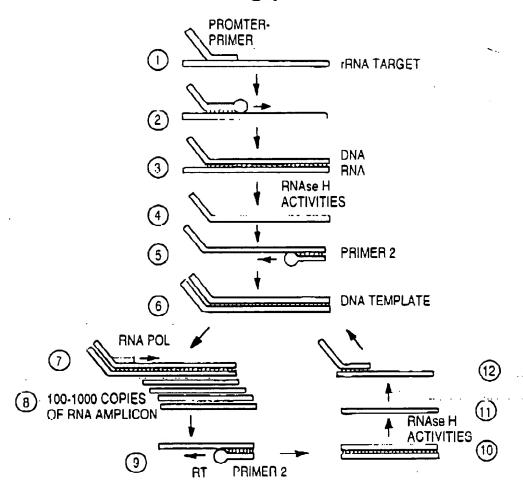
Initial Patent Examination Division (703) 308-1202

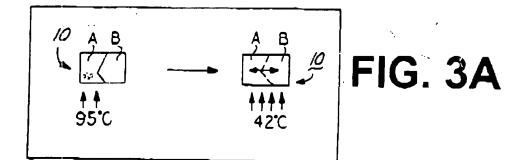
PART 2 - COPY TO BE RETURNED WITH RESPONSE

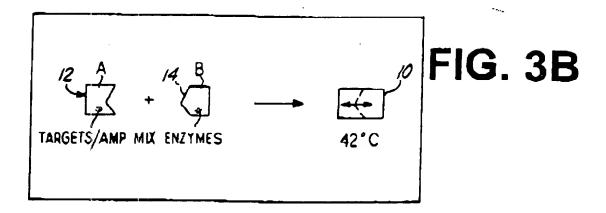
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FIG. 1









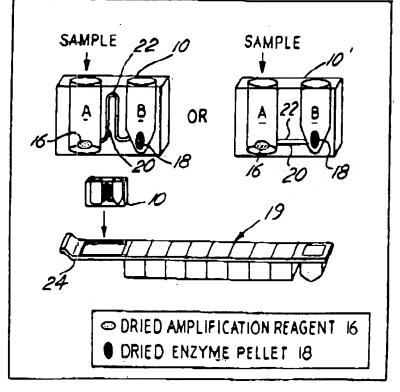
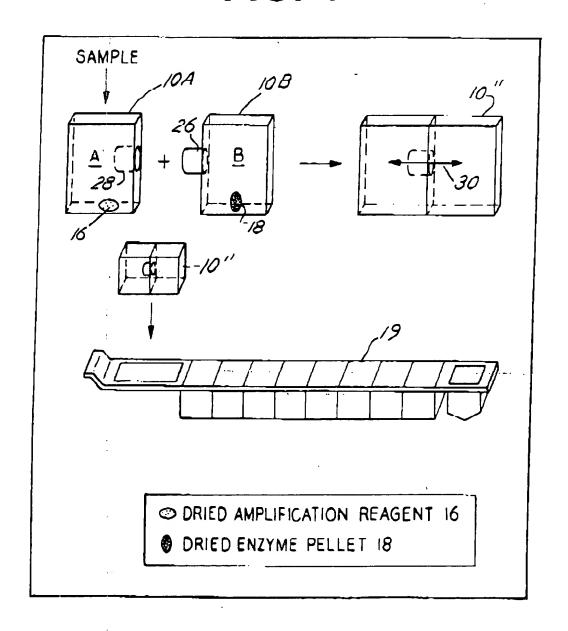
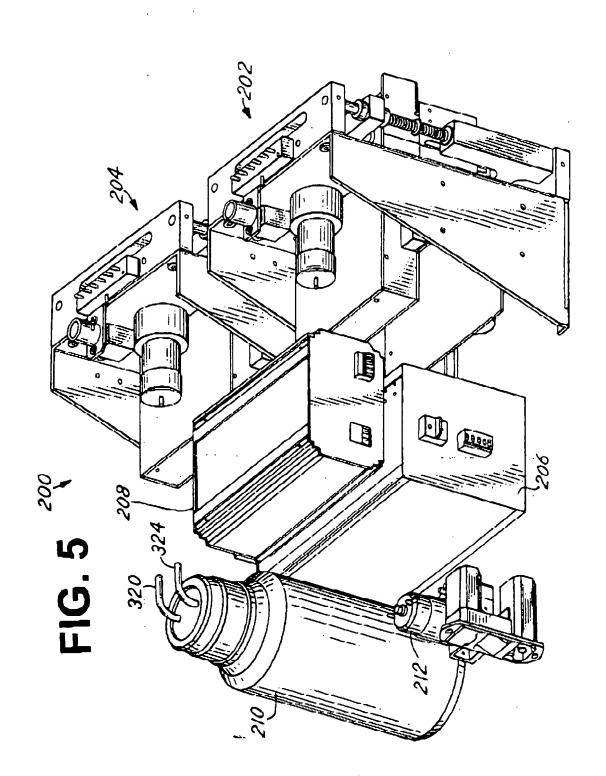
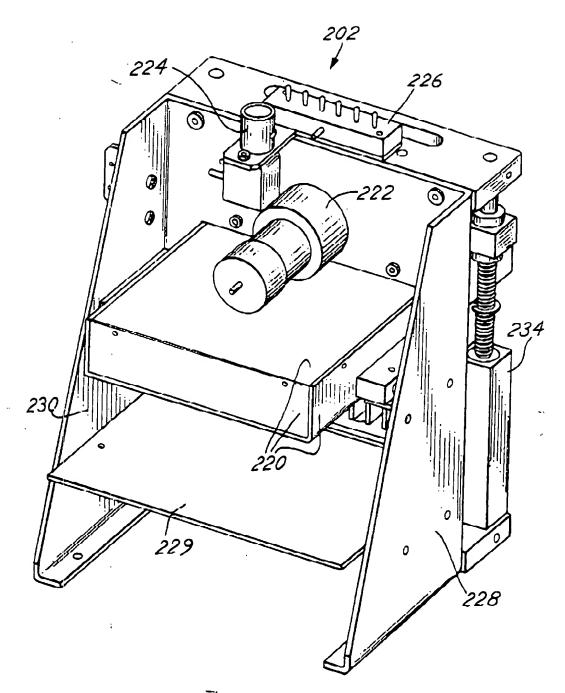


FIG. 3C







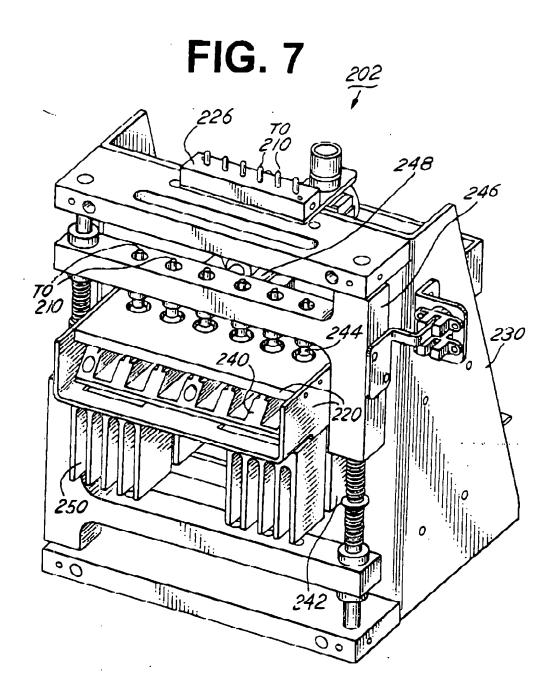
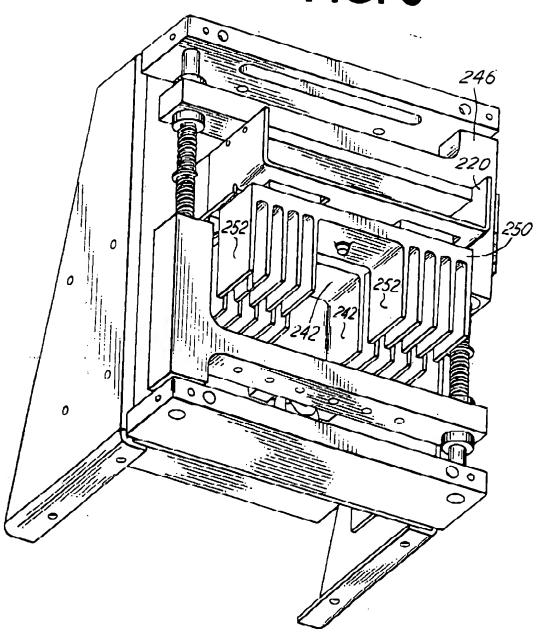
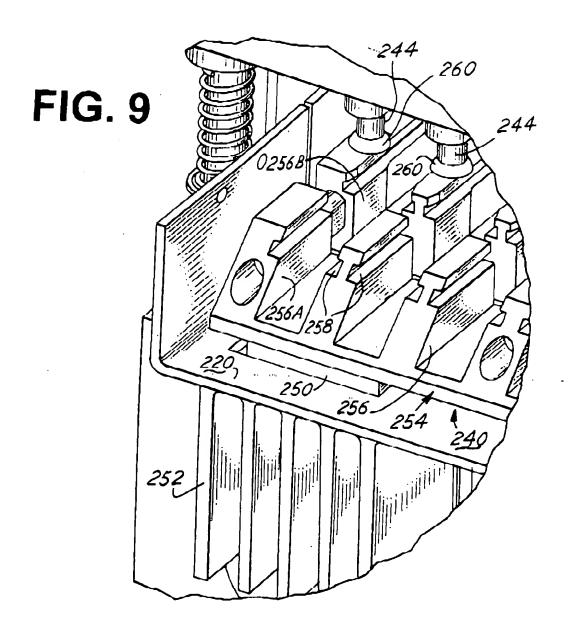
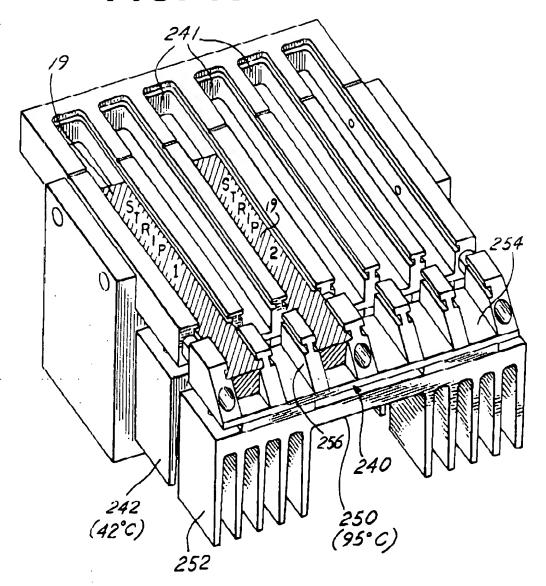
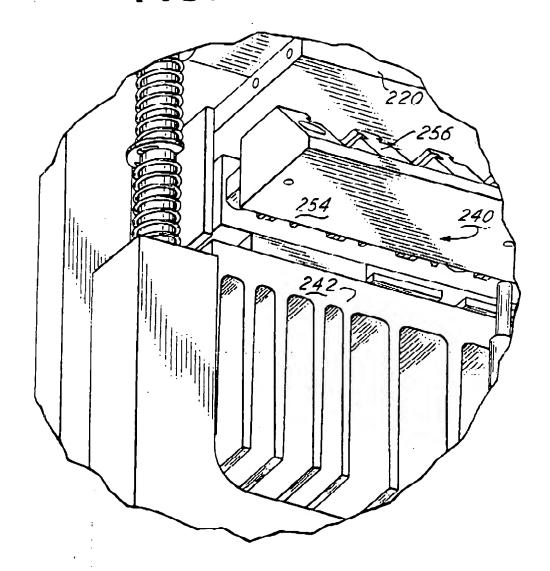


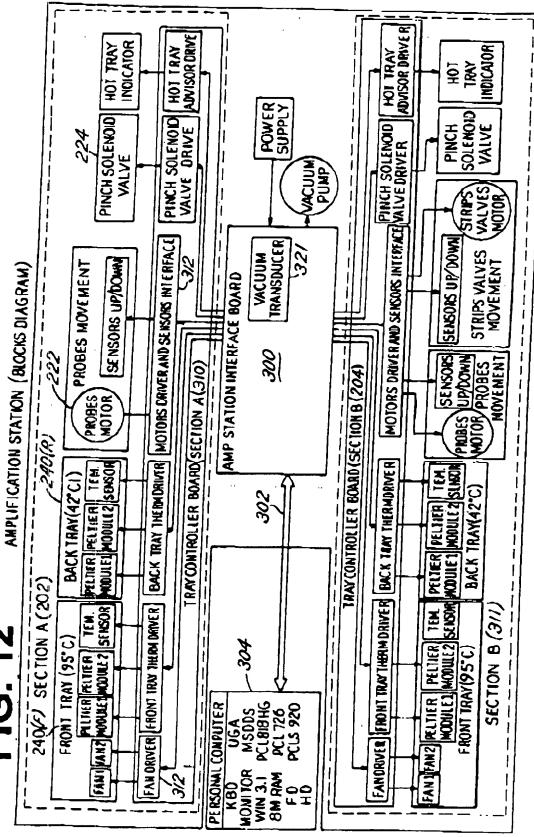
FIG. 8

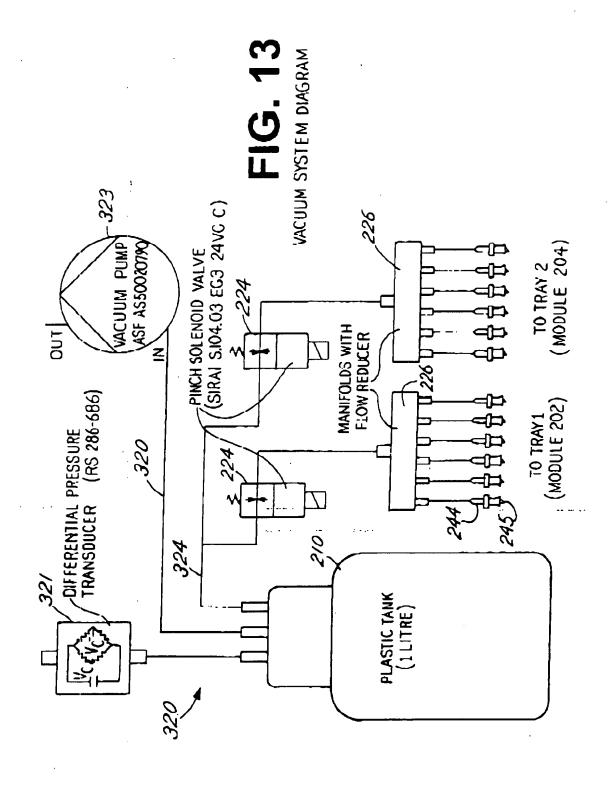




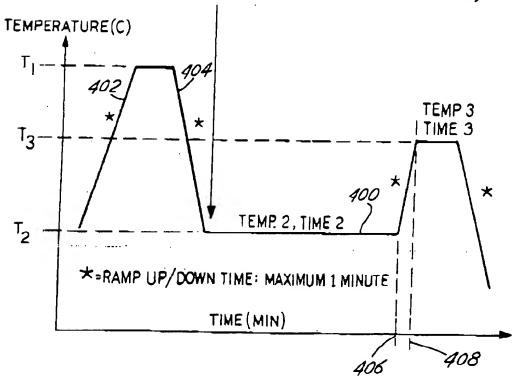












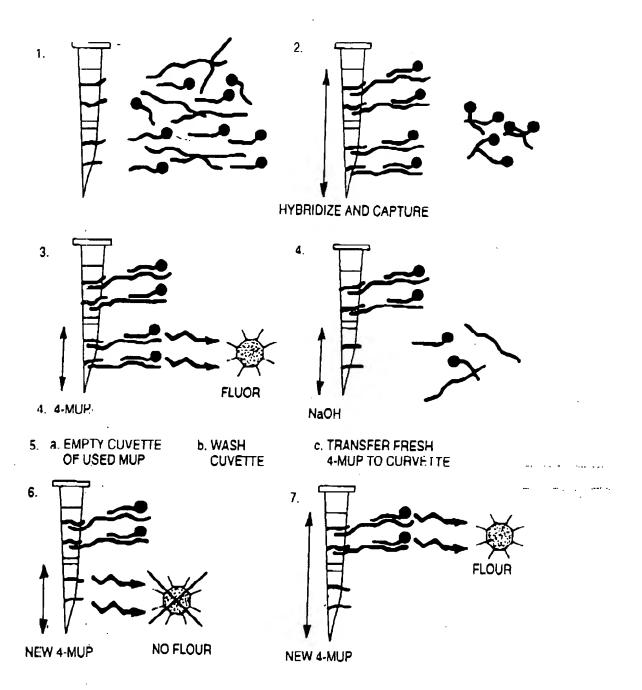
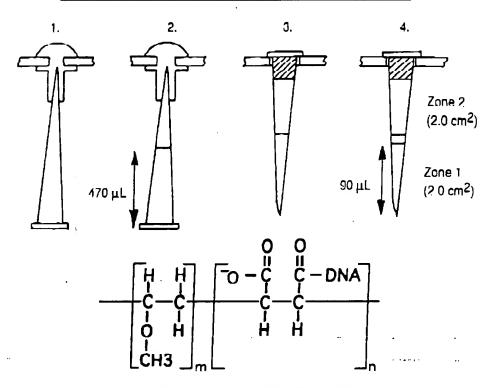


FIG. 15

SPR PRODUCTION WITH DISTINCT CAPTURE ZONES



CONJUGATE OF **AMVE** COPOLYMER AND SPECIFIC CAPTURE PROBE

MULTIPLEX STRIP CONFIGURATION

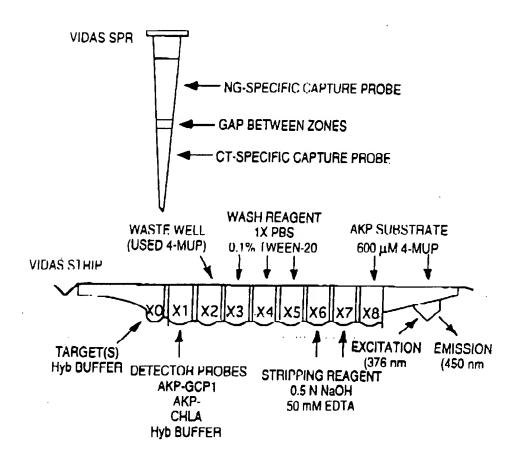


FIG. 17

TEST OF MULTIPLEX VIDAS PROTOCOL

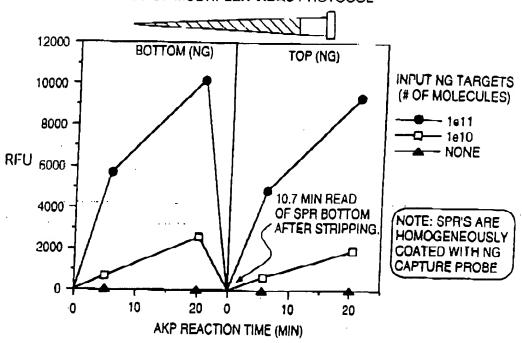
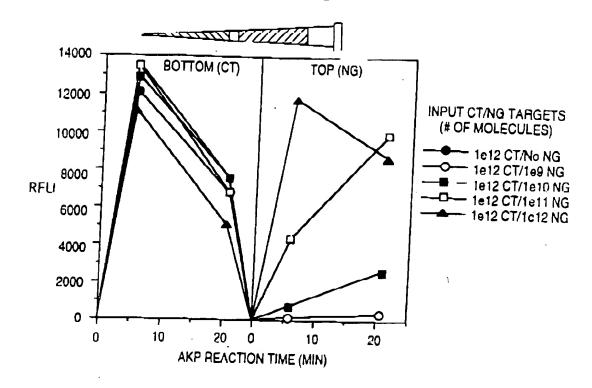


FIG. 18

FIG. 19A



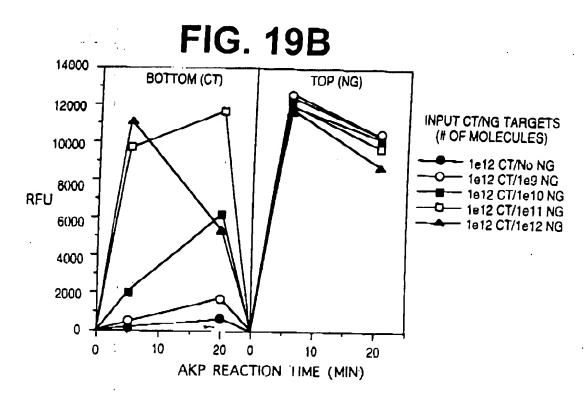


FIG. 20A

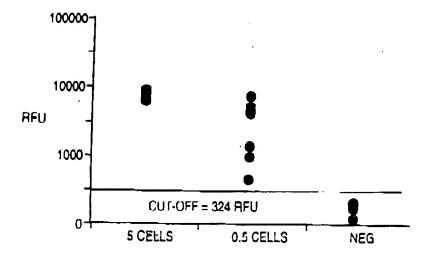
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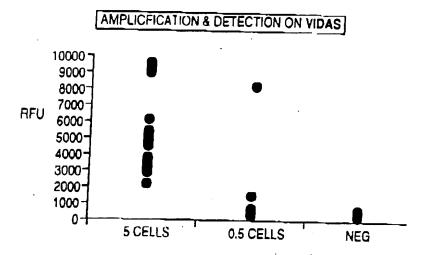
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FIG. 20B

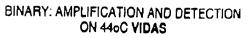
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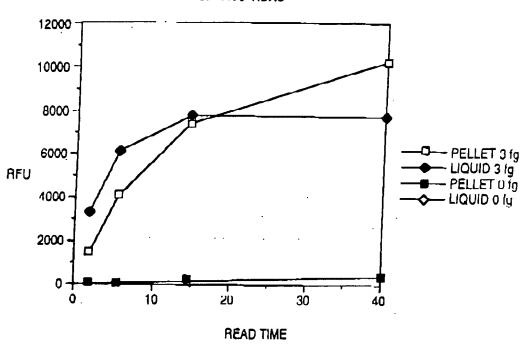


FIG. 22

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Random Internal Control

RABLE primer: 5'-AqCgAATGTTAgggCACACTC-3'

s'-gggagcgaatgttagggcacactcatgggtgagcaagtctttctggtaagggctgatgtcaggcgtattgacaagcatgacgaccaga-3' 5'-TAAGGGCTGAFGTCAGGCGTA-3' RAN21 ANVB-prode

RANJ) ARP-prode: 5'-ATGGGTGAGCAAGTCTTTCTG-3'

3' -AACTGTTCGTACTGCTGGTCT

A9A999ATATCACTCA9CATAATTTAA-5 (T) promoter / RANI9 primer)

(T) promoter)

5 '-CCAAITAACCCTCACTAAAGGGAGCGAAFGTTAGGGCACACTCATGGGTGAGCAAGTC-3 '

] -gtacccactcgitcagaangacattcccgactacagatacgcataactgttcgtactgttcgtact-5 ·

011003

5 -- AgC GAA TOT PAG 99C ACA CTC-3 RANIG THA primer:

3'-mainolink-tha ggg CTg ATG TCA ggc gTA-3' RANZI AKVE-probei

5'-aminolink-Arg ggr gAg CAA gTC TPT CTg-3' RANJ3 AKP-probe:

T7/RANIS THA PETERFE

5.-AAT TTA NTA CGA CTC ACT ATA 999 AGA TCT 99T CGT CAT GCT TGT CAA-3' AIC1 Detection oligo:

S'-GCA ATT AAC CCT CAC TAA AGG CAG CGA ATG TTA 999 CAC ACT CAT 999 TGA 9CA AGT C-1' 5'-CAN THE GCC 19A CAT EAG CCC TTA CAG ANA GAC TTG CTC ACC CAT GAG-1' RIC1 top oligo:

5'-ICT 99F C9F CAT 9CT TGT CAA TAC 9CC TGA CAT CA9 CCC TTA CA9 AAA 9AC TT9 CTC ACC CAT 9-3' RIC1 bottom oligo:

мвнв

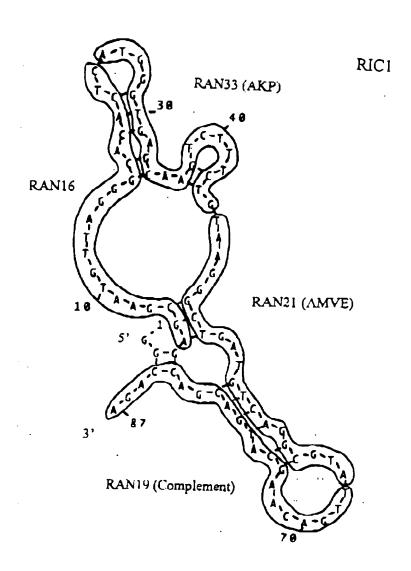


FIG. 25

3 - ACGATGGTC799ATCTCCTCACGCA

Random Internal Control 2

s - Cagtagagtagggctgctaggagtathacagalagccagtgtacggalcgactcagcacggcgaathctttgctaccagacctagaggagtbcgt— 3 ·) - gtcatctccatccccgacgatcctcataftgtcttcggtcalgccttgctgagtccgcttalgcalaigaaacgatggtctggatctcctcacgca—5 ·

RAMSI TWA PLIMOL 5'-CAGTAGAGGTAGGGGCTGCTAGGAGT-3'

----> 5'-cagtagataggutgctactagtatancagaagtatancagangceagtgtacgancgacacagcaatactttgctaccagacctagagaatgcgt-3' 5 -- ACGACTCAGCACGGCGAATAC-3 RAN32 AKF-prode TARGET ---

RAN2? ANVE-prode 5 - TRACAGRAGCCR9T9TRC99A-3:

A9A999MEATCACTCAGCATAATTTAA-5'

3 - GCAATTAACCCINCACTRAAGGGCAGTRGAGGTAGGGGCTGCTAGGAGTATRAACAGAAGCCAGTGTAC-3 ·

(T) promoter)

GLI 608

5'-CAG TAG AGG ZAG GGG CTG CTR GGA GT-3' RANS I THA primer:

5'-aminolink-taa cag aagacca 979 tac 99a-3' RAN27 ANVE-probe. RANJ2 ARP-prober

5 - AAF TTR ATA CGA CTC ACT ATA 999 AGA ACG CAC TCC TCT AGG TCT 99T AGC A-1 5'-amirolink-acy act cag cac 99c gab. Tac-3' T7 / RANJ9 primer:

5'-ANG TAT TCG CCG TGC TGA GTC GTT CCG TAC ACT 99C TTC TGT TAT AC-3' RIC2 Detection oligo: RIC2 Top oligo:

RIC2 Bottom oligor

S'-GCA ATT AAC CCT CAC TAA AGG OCA GTA GAG GTA 999 GCT GCT AGG AGT ATA ACA GAA GCC AGT GTA C-)' 5'-ACG CAC TOC TOT AGG TOT GGT AGG AAA GTA TTO GCC GTG CTG AGT CGT TOC GTA CAC 799 CTT CTG-3'

FIG. 26

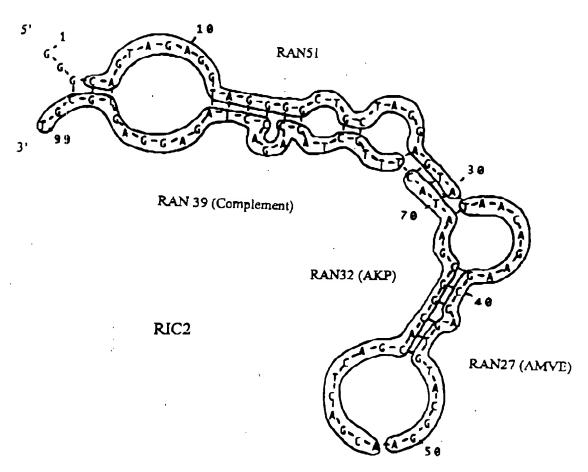


FIG. 27

Detection of RIC1 DNA Oligo Targets

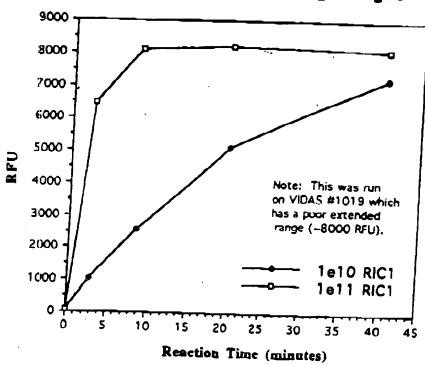


FIG. 28

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1010 Mar 10 Mar	SPR COat	ed at 0.5 ng/µ1	instead of the "	normal" 1 0 rozz	Person			: ! !	:

FIG. 29

FIG. 30

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 97,195-P)

In re Applica	ation of:)	
Bur	g, et al.)	
Serial No.:	09/901,181) Examine	r: TBA
Filed:	July 9, 2001) Art Unit	: 1656
For: Imp	roved Nucleic Acid Assavs)	

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents Washington, D.C. 20231

Attention: Application Processing Division

Customer Correction Branch

Dear Sir:

- 1. Attached is a copy of the official filing receipt received from the PTO in the above-referenced application for which issuance of a corrected filing receipt is respectfully requested.
- 2. There is an error with respect to the following data, which is incorrectly entered.

Error In:

THIS APPLICATION IS A CON OF 09/245,939 02/05/199

Correct Data:

THIS APPLICATION IS A CON OF 09/245,939 02/05/199, WHICH IS A DIVISIONAL OF 08/850,171 FILED MAY 2, 1997, NOW ABANDONED

3. The correction is not due to any error by applicant and no fee is due.

Respectfully submitted,

Date: September 10, 2001

Lisa M.W. Hillman Registration No. 43,673

McDonnell Boehnen Hulbert & Berghoff 300 South Wacker Drive, 32nd Floor Chicago, IL 60606 (312)913-0001



20306

SUITE 3200

United States Patent and Trademark Office

COMMISSIONER FOR PATENTS United States Patent and Trademark Office WASHINGTON, D.C. 20231

www.uspto.gov IND CLAIMS

APPLICATION NUMBER

300 SOUTH WACKER DRIVE

FILING DATE

GRP ART UNIT

FIL FEE REC'D ATTY.DOCKET.NO

DRAWINGS 29

TOT CLAIMS 18

09/901,181

CHICAGO, IL 60606

07/09/2001

MCDONNELL BOEHNEN HULBERT & BERGHOFF

1656

710

97,195-P

CONFIRMATION NO. 6516

FILING RECEIPT

OC000000006388905

Date Mailed: 08/06/2001

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Applicant(s)

J. Lawrence Burg, Framingham, MA; Bryan W. Kluttz, Norwell, MA; Luigi Catanzariti, Doxbury, MA; Marcela Vera-Garcia, Framingham, MA; James G. Moe, Franklin, MA; Geoff A. McKinley, Doxbury, MA;

Domestic Priority data as claimed by applicant

THIS APPLICATION IS A CON OF 09/245,939 02/05/1999 2 14 CH 15 A DIVISION AL

OF 08/850, 171 FILED MAY 2:1997, NEW ABLUDAND

Foreign Applications

If Required, Foreign Filing License Granted 08/03/2001

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

Early Publication Request: No

Title

Nucleic acid assays

AUG 0 0 0001 # ps no = - 10/9/01 Briga Kingle 6/27/62 MBHB

@046 Page 2 of 3

Preliminary Class

435

Data entry by : TAN, LEA-YUET

Team : OIPE

Date: 08/06/2001

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Patents and Trademarks
Re: Applicant— Runcy Land.

Improved NUCLEIC Acid Assays

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Attorney for Applicant

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